

## REMARKS

Upon entry of this Amendment, claims 1, 2, and 4-15 remain in the Application.

The Office Action of October 14, 2004 has been received and carefully considered. In response thereto, this Amendment is submitted. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Reconsideration is, therefore, respectfully requested.

Claims 1, 2, and 4-14 currently stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claims have been amended paying careful attention to the points made by the Examiner on pages 2 and 3 of the Office Action. It is respectfully submitted that, by these amendments, the Applicant's invention as set forth in claims 1, 2, and 4-14 now comport with the requirements of 35 U.S.C. § 112, first paragraph.

Claims 2 and 4-14 currently stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention. Claim 2 has been amended paying careful attention to the observations made by the Examiner. It is submitted that, by this Amendment, the Applicant's invention as set forth in claims 2 and 4-14 now particularly point out and distinctly claim the subject matter that the Applicant regards as the invention.

Claims 1, 2, 6-9, and 11-15 currently stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,126,597 to Smith et al. The Examiner contends that the Smith reference teaches a hygiene item comprised of an absorbent element configured to absorb and retain bodily fluid passed by a user. Commonly worn panties are considered absorbent and capable of retaining at least some bodily fluid that may be passed by a user. The analysis device includes means for analyzing at least one characteristic, such as pH of bodily fluid passed by the user. The Examiner indicates that the means in Smith facilitates direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent elements. The means as well as placement of the analysis device disposes the analysis device on the absorbent element. The Examiner indicates that the means 26, 28 separate the body fluid in the analysis device 34 from the absorbent element in an essentially fluid tight

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manner such that the means 28 may be composed of a polyethylene film that is liquid impervious. Since the separating means 26, 28 is liquid impervious and placed between analysis device 34 and absorbent means 12, it is also considered to be configured to retain any bodily fluid that penetrates the absorbent means 12 away from the analysis device 34 thereby preventing body fluid contaminated by the absorbent element 34 from falsifying an analysis of the analysis device 34.

It is the Examiner's position that the pant or undergarment 12 disclosed in Smith can be viewed as a "single-use hygiene item comprising a disposable absorbent element." The term "disposable" used in the hygiene article art clearly describes in structural terms that a respective article is configured and assigned for one-time use only and for discarding thereafter. Such term, therefore, should be interpreted as clearly distinguishing the subject article from a garment that is intended for multiple use, as the Smith garment is, when it describes the panty/undergarment as being of the type commonly worn by many women and well-known as a panty. (See Smith, line 30.) It is submitted that the Smith reference lacks any teaching or suggestion that would lead the skilled artisan to the conclusion that the panty 12 should be discarded after every use. Without further references directed to such uses, it is submitted that the Smith reference fails to teach or suggest that the panty/undergarment is disposable.

It should also be noted that the panty/undergarment of Smith lacks any teaching or suggestion of containing absorbent material that delivers substances to the bodily fluid to be contained therein that would change the composition of the bodily fluid thereby. It can be appreciated that changing the composition of the bodily fluid can interfere with analytical procedures. In contrast, the Smith reference, that is directed to the detection of amniotic fluid by pH change lacks any teaching or appreciation that various absorbent and superabsorbent materials can give off substances or byproducts when contacted with bodily fluid that would alter or change the composition of the fluid thereby compromising any analytical results. The present invention, in contrast, addresses this issue.

As set forth in claim 1 as amended, the Applicant's invention is directed to a single-use hygiene item that comprises a disposable absorbent element configured to absorb and retain bodily fluid passed by a user. The disposable element also contains absorbent material

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that gives off substances into the bodily fluid passed by the user and thereby changes the composition of the bodily fluid. Support for this Amendment is found in the specification at page 3, paragraph 11, and page 5, paragraph 18, lines 8-12. The single-use hygiene item also includes an analysis device for analyzing at least one characteristic of the bodily fluid passed by the user. The analysis device facilitates *direct* impingement of a portion of the bodily fluid passed by the user into contact with the analysis means *separate from contact with the absorbent element*. It is submitted that the Smith reference lacks any teaching, suggestion, or appreciation of this feature. Furthermore, the analysis device is configured for separating the bodily fluid in the analysis device to be analyzed from the disposable absorbent element in an *essentially fluid-tight manner*.

It can be appreciated that the Smith reference is directed to a pad and panty configuration in which a lower layer 28 may have fluid impervious characteristics. However, the Applicant respectfully disagrees with the Examiner in that the upper layer 26 cannot possess fluid imperviousness if the analytical device 34 is to function. Reference is directed to Figs. 2 and 3 where it can be appreciated that the bodily contour of the user can deform the Smith device thereby compromising any partial fluid imperviousness and containment functions present in that device. Thus, it is submitted that the Smith reference fails to teach or suggest the invention as set forth in claim 1 as amended, and that claim 1 is not taught, anticipated, or rendered obvious by the Smith reference.

Claims 2, 6-9 and 11-14 currently stand rejected under 35 U.S.C. § 102(e) as being unpatentable over Smith et al. Claims 2, 6-9 and 11-14 depend either directly or indirectly from claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the Applicant's invention as set forth in these claims is not taught, anticipated, or rendered obvious by the cited references for the reasons discussed previously in conjunction with claim 1.

Claim 15 currently stands rejected under 35 U.S.C. § 102(e) as being anticipated by the Smith reference. Claim 15 is directed to an analysis device that comprises a visual display unit for measuring the composition of bodily fluids directly introduced into the analysis device associated with the visual display unit. The device also includes means for maintaining the analysis device in a separate fluid-tight contact with a single-use hygiene item. The single-use

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hygiene item includes an absorbent element configured to absorb and retain bodily fluids other than those directly introduced into the analysis device in which the absorbent element contains absorbent material that gives off substances into the bodily fluid passed by the user and thereby changes the composition of the bodily fluid. Support for claim 15 as amended is found in the Specification at page 5, paragraph 18, and page 3, paragraph 11. It is respectfully submitted that the Smith reference fails to teach or suggest a single-use hygiene item that includes an absorbent element composed of an absorbent material that gives off substances when contacted with bodily fluid. For these reasons, it is submitted that Applicant's invention as set forth in claim 15 is not taught, anticipated, or rendered obvious by the Smith reference.

Claims 4 and 5 currently stand rejected under 35 U.S.C. § 103(a) as being anticipated by Smith in view of Mims, Jr. Claims 4 and 5 depend from independent claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the Applicant's as set forth in claims 4 and 5 is not taught, anticipated, or rendered obvious by the cited references for the reasons discussed previously in conjunction with claim 1.

Claim 10 also stands rejected under 35 U.S.C. § 103(a) as being rendered obvious by Smith in view of Todd. Claim 10 depends from independent claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the Applicant's invention as set forth in claim 10 is not taught, anticipated, or rendered obvious by the cited reference for the reasons discussed previously in conjunction with claim 1.

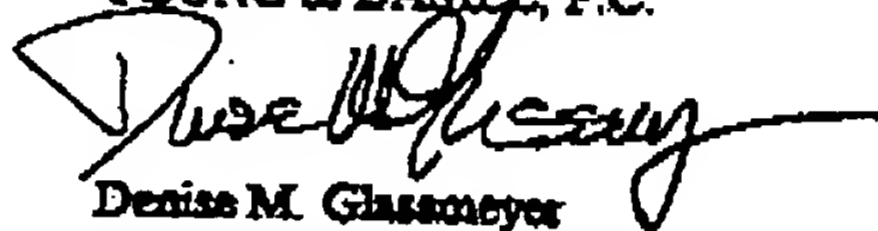
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In summary, claims 1, 2, and 15 have been amended. Arguments have been presented as to why the Applicant's invention as set forth in the claims is not taught, anticipated, or rendered obvious by the cited references. It is submitted that, by this Amendment, the Applicant's invention as set forth in claims 1, 2, and 4-15 is not taught, anticipated, or rendered obvious, and is in a condition suitable for allowance. Notice of allowance is, therefore, respectfully requested.

Respectfully submitted,

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Dated: January 14, 2005  
DMG/ljo